JACC Vol. 28, No. 4
October 1996:820–6

Long-Term (4- to 6-Year) Outcome of Palmaz-Schatz Stenting: Paucity of Late Clinical Stent-Related Problems

ROGER J. LAHAM, MD, JOSEPH P. CARROZZA, MD, FACC, CLIFFORD BERGER, MD, DAVID J. COHEN, MD, MSc, FACC, RICHARD E. KUNTZ, MD, MSc, FACC, DONALD S. BAIM, MD, FACC

Boston, Massachusetts

Objectives. **The purpose of this prospective single-center study was to evaluate the longer-term outcome of Palmaz-Schatz stenting in the treatment of native coronary and saphenous vein bypass graft disease.**

Background. **The STRESS (Stent Restenosis Study) and BENESTENT (Belgian Netherlands Stent) trials have demonstrated a decrease in both angiographic restenosis and the need for repeat revascularization in the 1st year for vessels treated by stenting rather than balloon angioplasty. Longer-term (1 to 5 years) clinical results of Palmaz-Schatz stenting are not yet well established. Late migration of the stent, metal fatigue, endarteritis and late restenosis have all been proposed as potential late clinical complications of coronary stent implantation.**

Methods. **The study cohort consisted of 175 consecutive patients who underwent elective placement of 194 Palmaz-Schatz stents in 185 vessels. Clinical events (death, myocardial infarction, recurrent angina or any revascularization) were assessed at 6 weeks, 2, 4 and 6 months, 1 year and yearly thereafter. Clinical follow-up was available on all patients at a mean ± SD of 54 ± 17 months.**

Results. **Angiographic success was achieved in 173 patients (98.9%); angiographic restenosis was observed at 6 months in 26.1% of target sites. The survival rate was 86.7% at 5 years, with a 5-year event-free survival rate decreasing progressively to 50.7%, reflecting primarily repeat revascularization procedures (41.2% at 5 years). However, the rate of repeat revascularization of the treatment site (target site revascularization [TSR]) was 14.4%, 17.7% and 19.8% at 1, 3 and 5 years, respectively, with late (>1 year) TSR driven by in-stent restenosis in only 3 patients (1.7%). Rates of both 5-year survival (70.5% vs. 93.4%) and event-free survival (21.1% vs. 63.3%) were lower for patients who underwent saphenous vein graft (SVG) stenting than for those with native coronary artery stenting. However, 5-year TSR rates were similar for SVGs (21.9%) and native vessels (19.2%), indicating that the higher incidence of repeat revascularization for SVGs was due to an increase in non-TSR, driven by progressive disease at other sites.**

Conclusions. **The long-term outcome of stenting shows stability of the treated lesion, with only a slight increase in TSR between 2 and 5 years (17.1% to 19.8%). The progressive increase in repeat revascularization over that period (24% to 41%) and most ongoing late events can be attributed to the progression of coronary disease at other sites, rather than to late deterioration of the stent result itself. Such non-TSR events account for the majority of clinical events in the patients who underwent SVG stenting.**

(J Am Coll Cardiol 1996;28:820–6)

Percutaneous endovascular stenting was conceived almost 2 decades ago (1–5) as a way to prevent both acute occlusion and late restenosis after catheter intervention, but the initial clinical reports of coronary artery stenting in 1987 were plagued by high (>20%) acute and subacute thrombosis (6). Over the past several years, stent outcomes have improved progressively (7,8), culminating in the recent STRESS (Stent Restenosis Study) (9) and BENESTENT (Belgian Netherlands Stent) (10) trials, which demonstrated that Palmaz-Schatz stenting of native coronary arteries is associated with greater procedural success, fewer acute adverse events, less angiographic restenosis and lower rates of 8-month target vessel revascularization than is conventional balloon angioplasty. In addition, Palmaz-Schatz stenting of aortocoronary saphenous vein grafts (SVG) has been reported to have a higher success rate and lower restenosis rate than those historically reported for balloon angioplasty (11). Whereas these favorable results are based on measurements at 6 to 9 months, the longer-term (1 to 5 years) results of Palmaz-Schatz stenting are not well established. Late migration of the stent, metal fatigue, endarteritis and late restenosis have each been proposed as potential long-term complications of coronary stent implantation (12).

To address these concerns about long-term outcome, we undertook this prospective single-center study of the longer-term results in our cohort of patients treated by Palmaz-Schatz stenting.

From the Cardiovascular Division of the Department of Medicine, Harvard Medical School and Beth Israel Hospital, Boston, Massachusetts.

Manuscript received January 31, 1996; revised manuscript received April 26, 1996, accepted May 7, 1996.

Address for correspondence: Dr. Donald S. Baim, Cardiovascular Division, Harvard Medical School, Beth Israel Hospital, 330 Brookline Avenue, Boston, Massachusetts 02215.

0735-1097/96/$15.00
PII S0735-1097(96)00244-6

Abbreviations and Acronyms

BENESTENT = Belgian Netherlands Stent study
CABG = coronary artery bypass grafting
CK-MB = creatine kinase, MB fraction
STRESS = Stent Restenosis Study
SVG = saphenous vein graft
TIMI = Thrombolysis in Myocardial Infarction
TSR = target site revascularization
TVR = target vessel revascularization

Methods

Patient selection. Between June 1988 and April 1991, 175 consecutive patients underwent elective placement of 194 investigational Palmaz-Schatz coronary stents in 185 vessels at Boston's Beth Israel Hospital, under a study protocol approved by the Committee for Human Research. Patients were considered for stenting if they had significant (>70%) diameter stenosis in a native coronary artery or SVG accompanied by evidence of myocardial ischemia. Exclusion criteria included contraindication to antiplatelet or anticoagulation therapy, poor distal runoff, small (<2.75 mm) or diffusely diseased vessels. All patients provided written informed consent.

Pharmacologic protocol. All patients received soluble, non-enteric–coated aspirin (325 mg, continued indefinitely), dipyridamole (200 mg daily, continued for 1 to 2 months) and a calcium antagonist before the procedure. In addition, low molecular weight dextran (Dextran 40) was given at a dose of 100 ml/h for 2 h before stenting and at a dose of 50 ml/h during and after the procedure, for a total volume of 1 liter. A first-generation cephalosporin or vancomycin was started 1 h before the procedure and continued for 48 h. During the procedure, 10,000 U of heparin was administered intravenously, with additional heparin given to maintain an activated clotting time >300 s. Therapy with warfarin was started the day of the procedure and continued for 1 to 2 months. An infusion of heparin was discontinued once the prothrombin time reached 16 to 18 s.

Stent implantation. All patients received Palmaz-Schatz stents (Johnson & Johnson Interventional Systems, Warren, New Jersey) through a variety of delivery techniques (hand-crimped bare stents, 6F Schneider Teleguide, Johnson & Johnson Interventional Systems Stent Delivery System). Lesions were predilated with the use of a 2.5-mm balloon. After deployment of the stent, adjunctive postdilation was performed (1.1:1 balloon/artery ratio), to achieve a visually-estimated angiographic residual diameter stenosis <10%. Creatine kinase, MB fraction (CK-MB) levels were routinely monitored for 24 h after the procedure and a CK-MB >13 IU/dl was considered diagnostic for a myocardial infarction.

Follow-up. All patients were contacted by the investigators at 6 weeks, 2, 4 and 6 months, 1 year and then yearly thereafter to assess clinical events (death, myocardial infarction, recurrent angina, or any revascularization including coronary artery bypass grafting (CABG) or percutaneous angioplasty). All revascularizations were categorized according to whether they involved the target site (TSR) or target vessel (TVR). Target vessel revascularization was defined as any revascularization that involved the target vessel, and target site revascularization was defined as any revascularization on the target vessel driven by stenosis within the index stent or within 5 mm on each side (proximal and distal) of the stented area. Death from any cause was considered an end point. Clinical follow-up was available for the entire cohort of 175 patients, and included follow-up of ≥4 years in 173 patients (99%), excluding 2 patients who were lost-to-follow-up at 22 and 40 months after the index procedure. At last contact, both of these patients were event-free. Survival and event-free survival were calculated from the date of the procedure to the date of death, adverse event or last follow-up.

Angiographic analysis. Angiography was performed in two orthogonal views. Each stented lesion was measured from an optically magnified cine frame showing the lesion in its tightest view with the guiding catheter used as a reference object. Measurements were performed by using digital calipers (Fowler Ultra-Cal II) and included guiding catheter diameter, proximal and distal reference segment diameter and minimal lumen diameter before and after stenting (8).

Factors analyzed and statistical methods. Data are expressed as mean value ± SD. Continuous variables were compared by unpaired Student *t* test, categoric variables by chi-square analysis (13). Survival and event-free survival were estimated by Kaplan-Meier curves (13) and compared by using the log-rank test. The independent association between [age, gender, smoking, diabetes mellitus, unstable angina/recent myocardial infarction and in-hospital outcome] and survival, event-free survival and TSR, was tested by using stepwise Cox proportional hazard regression analysis (14). Logistic regression was used to determine predictors of acute adverse events. All reported p values were two-tailed, and a p value ≤ 0.05 was considered statistically significant.

Results

Patient characteristics. The study cohort consisted of 175 patients who underwent placement of 194 Palmaz-Schatz coronary stents in 185 vessels (left anterior descending coronary artery 39 [21%], left circumflex coronary artery 19 [10%], right coronary artery 68 [37%] and SVG 59 [32%]). Their baseline characteristics are summarized in Table 1. The mean age was 59 ± 11 years; 34 patients (19.4%) were women. Diabetes mellitus was present in 29 patients (16.7%), 37 patients (21.3%) had a recent myocardial infarction (within 6 weeks) and 115 patients (66.5%) presented with unstable angina. Previous coronary artery bypass grafting had been performed in 53 patients (30.6%). The majority of lesions (57.7%) represented recurrence after one or more prior catheter interventions.

Acute procedural outcome. Although these procedures were performed early in the investigational phase of coronary

Table 1. Baseline Clinical Characteristics

	Patients (n = 175)
Age (yr)	59 ± 11
Men/women	141/34
Diabetes mellitus	29 (16.7%)
Hypertension	80 (50%)
Current smoker	78 (45.4%)
Hypercholesterolemia	100 (58.5%)
History of myocardial infarction	71 (40.8%)
Recent myocardial infarction*	37 (21.3%)
Unstable angina	115 (66.5%)
Congestive heart failure at presentation	17 (11.5%)
Prior CABG (mean post-CABG interval 7.3 ± 4.2 yr)	53 (30.6%)
Number of diseased vessels	
1	79 (45.1%)
2	35 (20%)
3	61 (34.9%)
Target vessel (n = 185)	
Left anterior descending coronary artery	39 (21%)
Left circumflex coronary artery	19 (10%)
Right coronary artery	68 (37%)
Saphenous vein graft	59 (32%)
Restenotic lesion	101 (57.7%)

*Myocardial infarction within previous 6 weeks. Values presented are mean value ± SD or number (%) of patients or vessels. CABG = coronary artery bypass grafting.

stenting, the immediate results generally compare favorably with more recent experience. Angiographic success (<50% diameter stenosis with Thrombolysis in Myocardial Infarction [TIMI] grade 3 flow) was achieved in 173 patients (98.9%). The mean preprocedural stenosis was 78 ± 24%, and the mean postprocedural stenosis was −1 ± 1%. The lumen diameters at baseline and immediately after the procedure are shown in Figure 1. One patient died 8 days after the index procedure, yielding a procedural mortality rate of 0.6%. Emergency coronary artery bypass grafting was performed in one patient (0.6%) after an unsuccessful attempt to stent a post–coronary angioplasty dissection. There were no Q wave myocardial infarctions, but nine patients (5.1%) had a non-Q wave myocardial infarction (CK-MB >13 IU/dl). Subacute stent thrombosis occurred in 2 patients (1.1%), but hemorrhagic complications required blood transfusions in 19 patients (10.9%) and local vascular complications necessitated surgical repair in 22 patients (12.6%). Retroperitoneal hemorrhage occurred in five patients (2.9%), and four patients (2.3%) had major gastrointestinal bleeding. By multivariate logistic regression analysis, diabetes mellitus was the only independent predictor of postprocedural non-Q wave myocardial infarction (odds ratio 7.1, p = 0.01).

Figure 1. Cumulative frequency of minimal lumen diameter at baseline, after stent implantation and at follow-up.

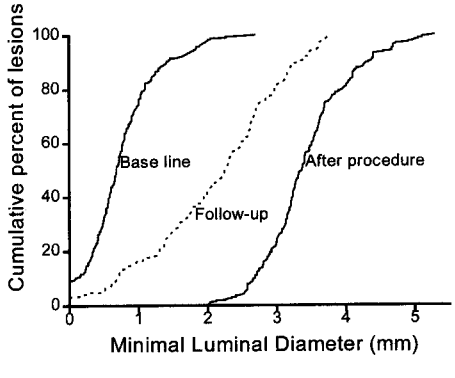


Table 2. Clinical Events

	Patients (n = 175)
Death	24 (13.7%)
Myocardial infarction	22 (12.6%)
Any revascularization	69 (39.4%)
Repeat PTCA	55 (31.4%)
CABG	22 (12.6%)
Target vessel revascularization	53 (30.3%)
Target site revascularization	33 (18.9%)
Any event	87 (49.7%)
Angina at conclusion of study	50 (28.6%)

Data presented are number (%) of patients. CABG = coronary artery bypass grafting; PTCA = percutaneous transluminal coronary angioplasty.

Angiographic follow-up. Routine follow-up angiography was performed in 151 patients (86.3%), providing data on 165 stented vessels (89.2%) after a mean follow-up period of 6.3 ± 3.1 months. The mean percent stenosis on follow-up angiography was 35 ± 26%. Angiographic restenosis (≥50% diameter stenosis) was observed in 43 (26.1%) of 165 stented vessels. The lumen dimensions at follow-up angiography are shown in Figure 1. Of 24 patients (14%) who did not undergo follow-up angiography, 19 patients have been followed up clinically for ≥4 years and have remained free of all adverse events including repeat revascularization. The remaining five patients without angiographic follow-up died (0.3, 3, 5, 24 and 32 months of clinical follow-up, respectively). One of the five died of cancer (0.3 month), one of complications of a myocardial infarction in a distribution distinct from the stented vessel (24 months) and three suddenly of undetermined cause (3, 5 and 32 months, respectively).

Late clinical follow-up. Late clinical follow-up was available for all patients at 54 ± 17 months, with ≥4 years of clinical follow-up available for 173 (99%). Data on all events at last follow-up are shown in Table 2. At the conclusion of the study, 24 patients (13.7%) had died after a mean of 21.3 ± 15.2 months (median 20). Major events (death, myocardial infarction and revascularization) had occurred in 87 patients (49.7%) after a mean of 17.4 ± 15.4 months (median 10.4). These events included repeat revascularization in 69 patients (39.4%) after a mean of 14.9 ± 14.2 months (median 7.2) and myocardial infarction in 22 patients (12.6%) after a mean of 22.2 ± 14.7 months (median 20.1). At last contact, 120 patients (68.6%) were alive and free of angina.

Of the 87 patients (49.7%) who had repeat revascularize-

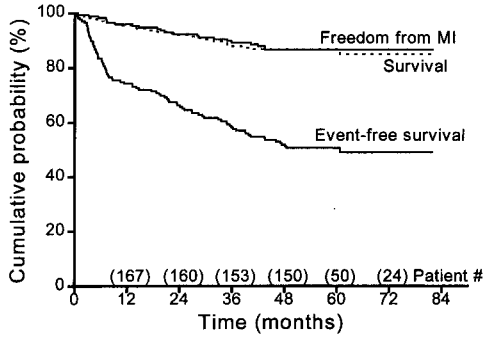


Figure 2. Cumulative probability of survival, freedom from myocardial infarction (MI) and event-free survival.

tion, only 33 (18.9%) underwent TSR, which comprised <50% of the repeat revascularization procedures. Whereas eight of these TSR events occurred >1 year (mean 28.5 ± 12 months, median 21.6 months) after the index procedure, only three patients (1.7%) had in-stent restenosis that developed after documented patency on 6-month follow-up angiography. The remaining late TSR events were performed on noncritical in-stent lesions: A 50% in-stent stenosis in an SVG stent was treated after stenting a new distal 95% stenosis; a stent placed for progressive distal disease was considered a TSR because it overlapped the index stent. In the remaining three patients, noncritically stenosed stents were bypassed during CABG, driven by progressive disease at other sites.

Actuarial survival, freedom from myocardial infarction and event-free survival (freedom from death, myocardial infarction and revascularization) are shown in Figure 2. By Kaplan-Meier estimates, the cumulative survival rate was 95.4%, 87.9% and 86.7% respectively, at 1, 3 and 5 years after stent implantation. By multivariate analysis, previous CABG (hazards ratio 4.3, $p < 0.001$) was the only independent predictor of late mortality. The probability of freedom from myocardial infarction was 95.9%, 89.2% and 86.6%, respectively, 1, 3 and 5 years. The cumulative probability of event-free survival was 74.3%, 58.2% and 50.7%, respectively, at 1, 3 and 5 years after the index procedure. Diabetes mellitus (hazards ratio 2.1, $p = 0.003$) and prior CABG (hazards ratio 2.6, $p < 0.001$) were the only independent predictors of adverse events. Figure 3 shows significantly better survival (97.6% vs. 90.4% at 1 year and 93.4% vs. 70.5% at 5 years, $p < 0.0001$) and event-free survival (76.4% vs. 69.2% at 1 year and 63.3% vs. 21.1% at 5 years, $p < 0.0001$) for native coronary stenting than for SVG stenting ($p < 0.0001$).

The cumulative probability of repeat revascularization, target vessel revascularization and TSR are depicted in Figure 4. The cumulative probability of undergoing any revascularization was 15.6%, 24.3%, 35.3% and 41.2%, respectively, at 6 months and 1, 3 and 5 years after stent implantation. By multivariate analysis, diabetes mellitus (hazards ratio 2.4, $p < 0.001$) was the only independent predictor of repeat revascularization.

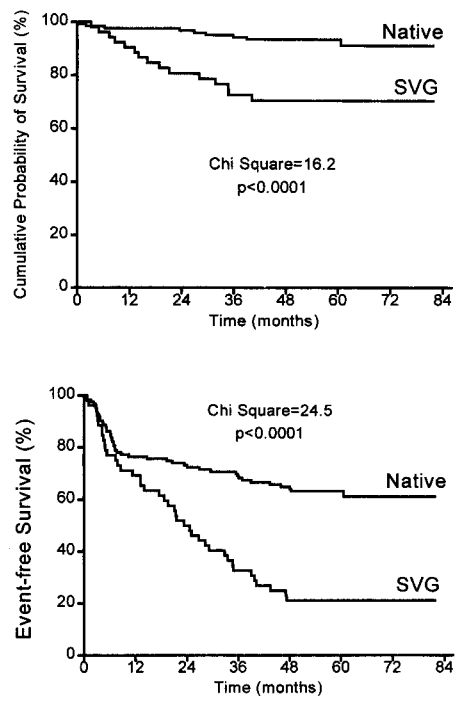
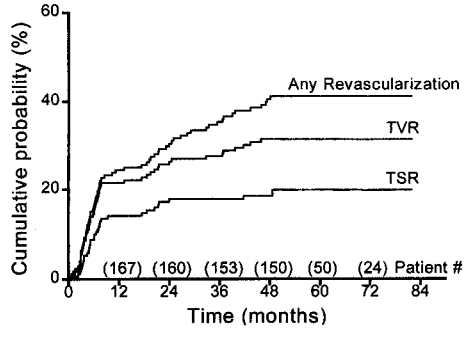


Figure 3. Cumulative probability of survival **(top)** and event-free survival **(bottom)** in native coronary artery stenting versus saphenous vein graft (SVG) stenting. The probability of both is higher for native coronary artery stenting.

The probability of TVR was 14.4%, 21.4%, 27.4% and 31.3%, respectively, at 6 months and 1, 3 and 5 years. In contrast, the probability of TSR was 8.7%, 14%, 17.1%, 17.7%, 18.4%, and 19.8%, respectively, at 6 months, 1, 2, 3, 4 and 5 years. Figure 5 shows the cumulative probability of revascularization, TSR and non-TSR for native coronary artery versus SVG stenting. The probability of undergoing repeat revascularization was higher for SVG stenting than for native coronary artery stenting (25.6% vs. 23.7% at 1 year and 67.4% vs. 31.5% at 5 years, $p = 0.0002$), attributable mainly to non-TSR (15.6%

Figure 4. Cumulative probability of total revascularization, target vessel revascularization (TVR) and target site revascularization (TSR). TSR reached a plateau after 1 year, suggesting that most ongoing late events can be attributed to the progression of coronary disease elsewhere rather than to late deterioration of the stent result.



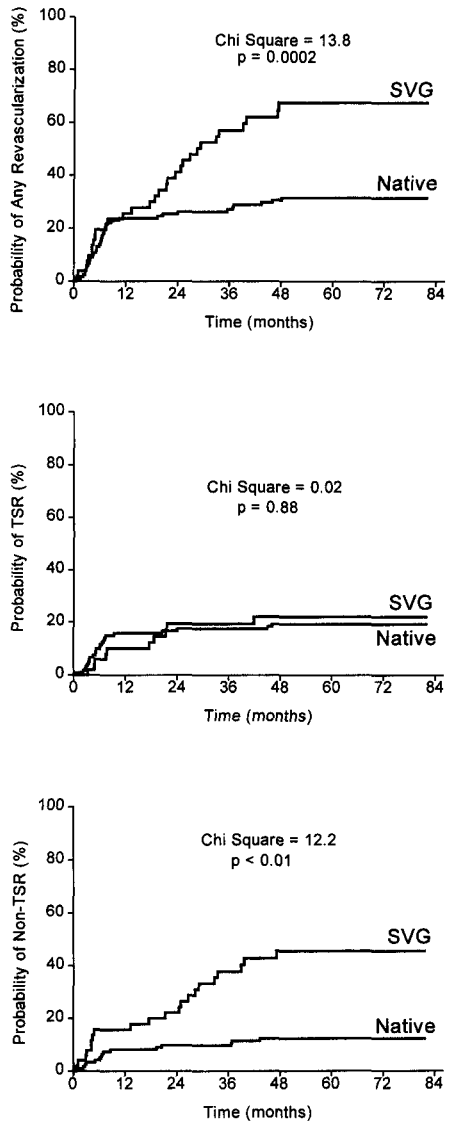


Figure 5. Probability of any revascularization **(top)** and of target site (TSR) **(middle)** and nontarget site (non-TSR) revascularization **(bottom)** in saphenous vein graft (SVG) versus native coronary artery stenting. The probability is higher for vein graft stenting for both any revascularization and non-TSR, but it is similar in the two groups for TSR.

vs. 8% at 1 year and 45.5% vs. 12.3% at 5 years, $p < 0.01$), as the probability of TSR was similar for both groups (10% vs. 15.7% at 1 year and 21.9% vs. 19.2% at 5 years, $p = 0.88$).

Discussion

The 1994 Food and Drug Administration approval of the Palmaz-Schatz stent for elective primary coronary artery revascularization in selected patients (15) represented a milestone in the percutaneous treatment of coronary artery disease. Including such "off-label" uses as treating restenosis and SVG stenting, an estimated 20% to 30% of coronary interventions now involve stent placement. The approval and rapid acceptance of stenting can be attributed largely to the STRESS (9) and BENESTENT (10) trials, which demonstrated that, compared with balloon angioplasty, stenting decreased both the incidence of angiographic restenosis and the need for repeat revascularization. However, both trials had a relatively short (7 to 8 months) follow-up period. The editorial (12) accompanying publication of the results of these trials and subsequent commentary (USA Today) (16) raised issues regarding the longer-term results of stenting, with specific concerns about the potential for late migration, metal fatigue, endarteritis, late restenosis and other late complications of prosthetic devices implanted in coronary arteries. The present study was thus conducted to evaluate the long-term safety and efficacy of Palmaz-Schatz stenting in the treatment of coronary artery and SVG disease.

Comparison with other studies. In the present study, the immediate procedural success rate was 98.9%, which is comparable to that in the STRESS (9) and BENESTENT (10) trials, as well as that in other stent series (7,11,15), but higher than the success rate of balloon angioplasty in the STRESS and BENESTENT trials or other angioplasty series (17–21). The rates of emergency CABG and in-hospital mortality (0.6%) were similar to the rates reported for other studies (7,9–11,15). We observed no Q wave myocardial infarctions, whereas, previous stent series (9,10) reported a 0.8% to 2.9% rate of postprocedural Q wave myocardial infarction. However, our 5.1% rate of postprocedural non-Q wave myocardial infarction was higher than that reported in the STRESS (2.5%) (9) and BENESTENT (2.3%) (10) trials, and this difference may reflect our treatment of SVG lesions as well as closer monitoring of postprocedural CK-MB in our series. The vascular complication rate in our patients was also high (but consistent with STRESS and BENESTENT rates), reflecting aggressive anticoagulation and sheath removal techniques prevalent at that time. The angiographic restenosis rate in our series was 26.1%, midway between that seen in the STRESS (31.6%) and BENESTENT (22%) trials and lower than the 34% restenosis rate reported with SVG stenting in the Multicenter Registry (11).

Complete clinical follow-up on our cohort over 4 to 6 years shows an overall survival rate of 95.4%, 87.9% and 86.7%, respectively, at 1, 3 and 5 years. This reflects a 3%/year mortality rate typical of coronary artery disease. Survival, however, was significantly lower for patients who underwent SVG rather than native coronary artery stenting (90.4% vs. 97.6% at 1 year and 70.5% vs. 93.4% at 5 years, $p < 0.0001$). The event-free survival rate was 74.3% at 1 year, which is lower than the 80.5% and 79.9% event-free survival rates in the stent arm of the STRESS (9) and BENESTENT (10) trials at 7 to 8 months. This difference probably reflects our inclusion of patients undergoing treatment of restenotic and SVG lesions with their attendant lower event-free survival rate (22). In contrast, event-free survival at 8 months after native coronary vessel stenting was 78% in our study, fully comparable to that

seen in the STRESS and BENESTENT trials. This event-free survival rate is higher than historically reported for other percutaneous revascularization devices. In the Coronary Angioplasty Versus Excisional Atherectomy Trial (CAVEAT I) (23), the 1-year event-free survival rate after balloon angioplasty and directional coronary atherectomy was 66.1% and 53.5%, respectively. The 1-year event-free survival rate after balloon angioplasty in the 1985–1986 National Heart, Lung, and Blood Institute registry was 66% (18). However, the event-free survival rate decreased further (58.2% at 3 years and 50.7% at 5 years) in our cohort, potentially supporting the concern that late stent-related complications might be developing.

The most common late event was repeat revascularization, whose cumulative probability was 24.3%, 35.3% and 41.2%, respectively, at 1, 3 and 5 years. However, <50 of procedures reflected repeat intervention *on the index stented segment.* The probability of repeat intervention on the stented site (TSR) was thus 8.7% at 6 months and 14% at 1 year, reaching a plateau at 17.1% to 19.8% over 2 to 5 years. Late (>1 year) TSR was driven by in-stent restenosis in only three patients (1.7% of the stented cohort), with most other late TSR being performed on mild "innocent bystander" lesions during procedures aimed primarily at treatment of other segments. These data confirmed the data of Kimura et al. (24), who reported 3-year follow-up after Palmaz-Schatz stenting and showed revascularization of the target lesion in only 2.1% of patients after 14 months. In our cohort, the rising rate of overall late revascularization (to 41.2% at 5 years) reflected mostly non-TSR (17.6% at 3 years and 21.4% at 5 years), indicating that late revascularization was performed predominantly to treat progressive disease at nontarget sites rather than late deterioration at the stent site itself. This was particularly common in patients who underwent SVG stenting, as we (22) have described previously.

The stable TSR rate after 1 year thus argues strongly against the suggestion that stenting simply delays rather than prevents restenosis (12), with no indication of late deterioration of the stented site. It also supports the long-term safety of stenting. However, even the best long-term stent results do not protect against progression of disease at other sites, particularly in patients undergoing stenting of SVG lesions.

Limitations of the study. There are several important limitations to this study. Palmaz-Schatz stenting in this group of patients was performed early in our experience with this device. It predated routine high pressure postdilation of the stent, intravascular ultrasound guidance and reduced anticoagulation regimens, which may have improved immediate results or long-term outcome of this procedure. Furthermore, the study patients represent a relatively selected group with respect to lesion morphology, severity of coronary artery disease and comorbidity. Stenting in other patient subsets (higher risk anatomy, abrupt closure after use of other devices and acute myocardial infarction) may have different procedural and long-term outcomes. In addition, because this study was limited to clinical follow-up, subclinical stent-related problems were not investigated. Additional follow-up (e.g., 10 years) may disclose the development of stent-related problems, but this appears unlikely in light of the 4- to 6-year data.

Conclusions. Palmaz-Schatz stenting result in better immediate and long-term results than does balloon angioplasty. The long-term (4- to 6-year) outcome of Palmaz-Schatz stenting shows stability of the treated lesion. Most ongoing late events can be attributed to the progression of coronary disease elsewhere, which would not be prevented by even a perfect (0% restenosis) device. There was no evidence of late clinical deterioration of the stent result itself at 4 to 6 years, a finding that should alleviate some of the concerns about late adverse consequences of stent implantation.

References

1. Dotter CT. Transluminally-placed coil-spring endarterial tube grafts: long-term patency in canine popliteal artery. Invest Radiol 1969;4:329–32.
2. Palmaz JC, Sibbett RR, Reuter SR, Tio FO, Rice WJ. Expandable intraluminal graft: a preliminary study: work in progress. Radiology 1985;156:73–7.
3. Wright KC, Wallace S, Charnsangavej C, Carrasco CH, Gianturco C. Percutaneous endovascular stents: an experimental evaluation. Radiology 1985;156:69–72.
4. Dotter CT, Buschmann RW, McKinney MK, Rosch J. Transluminal expandable nitinol coil stent grafting: preliminary report. Radiology 1983;147:259–60.
5. Palmaz JC, Windeler SA, Garcia F, Tio FO, Sibbitt RR, Reuter SR. Atherosclerotic rabbit aortas: expandable intraluminal grafting. Radiology 1986;160:723–6.
6. Sigwart U, Puel J, Mirkovitch V, Joffre F, Kappenberger L. Intravascular stents to prevent occlusion and restenosis after transluminal angioplasty. N Engl J Med 1987;316:701–6.
7. Schatz RA, Baim DS, Leon M, et al. Clinical experience with the Palmaz-Schatz coronary stent: initial results of a multicenter study. Circulation 1991;83:148–61.
8. Carrozza JP, Kuntz RE, Levine MJ, et al. Angiographic and clinical outcome of intracoronary stenting: immediate and long-term results from a large single center experience. J Am Coll Cardiol 1992;20:328–37.
9. Fischman DL, Leon MB, Baim DS, et al. A randomized comparison of coronary-stent placement and balloon angioplasty in the treatment of coronary artery disease. N Engl J Med 1994;331:496–501.
10. Serruys PW, De Jaegere P, Kiemeneij F, et al. A comparison of balloon-expandable-stent implantation with balloon angioplasty in patients with coronary artery disease. N Engl J Med 1994;331:489–95.
11. Fenton SH, Fishman DL, Savage MP, et al. Long-term angiographic and clinical outcome after implantation of balloon-expandable stents in aorto-coronary saphenous vein grafts. Am J Cardiol 1994;74:1187–91.
12. Topol EJ. Caveats about elective coronary stenting. N Engl J Med 1994;331:539–41.
13. Armitage P, Berry G. Statistical Methods in Medical Research. 2nd ed. Cambridge (MA): Blackwell Scientific. 1987.
14. Cox DR. Regression models and life tables. J R Stat Soc [B]. 1972;34:187–220.
15. Savage MP, Fischman DL, Schatz RA, et al. Long-term angiographic and clinical outcome after implantation of a balloon-expandable stent in the native coronary circulation. J Am Coll Cardiol 1994;24:1207–12.
16. USA Today, 1995 Sept 13;4D.
17. Detre K, Holubkov R, Kelsey S, et al. Percutaneous transluminal coronary angioplasty in 1985–1986 and 1977–1981. The National Heart, Lung, and Blood Institute registry. N Engl J Med 1988;318:265–70.
18. Detre K, Holubkov R, Kelsey S, et al. One-year follow-up results of the 1985–1986 National Heart, Lung, and Blood Institute's percutaneous transluminal angioplasty registry. Circulation 1989;80:421–8.
19. Kadel C, Vallbracht C, Buss F, Kober G, Kaltenbach M. Long-term

follow-up after percutaneous transluminal coronary angioplasty in patients with single vessel disease. Am Heart J 1992;124:1159–69.

20. Topol EJ, Leya F, Pinkerton CA, et al. A comparison of directional atherectomy with coronary angioplasty in patients with coronary artery disease: the CAVEAT study group. N Engl J Med 1993;329:221–7.
21. Landau C, Lange RA, Hillis D. Percutaneous transluminal coronary angioplasty. N Engl J Med 1994;330:981–93.
22. Piana RN, Moscucci M, Cohen DJ, et al. Palmaz-Schatz stenting for treatment of focal vein graft stenosis: immediate results and long-term outcome. J Am Coll Cardiol 1994;23:1296–304.
23. Elliot JM, Berdan LG, Holmes DR, et al. One-year follow-up in the Coronary Angioplasty Versus Excisional Atherectomy Trial (CAVEAT I). Circulation 1995;91:2158–66.
24. Kimura T, Yokoi H, Nakagawa Y, et al. Three-year follow-up after implantation of metallic coronary-artery stents. N Engl J Med 1996;334: 561–6.